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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,476	02/27/2002	Roger N. Piasio	ISA-102.01	4777

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FOLEY HOAG, LLP  
PATENT GROUP, (w/ISA)  
155 SEAPORT BLVD.  
BOSTON, MA 02210-2600

EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/083,476	<b>Applicant(s)</b> PIASIO ET AL.	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22 ~~is~~/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 ~~is~~/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Request for Continued Examination**

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 07/03/06 has been entered.

### **Applicants' Response**

2) Acknowledgment is made of Applicants' response filed 10/16/06 in response to the final Office Action mailed 12/29/05.

### **Status of Claims**

3) Claims 16-21 have been canceled via the amendment filed 10/16/06.  
Claim 22 is pending.

### **Prior Citation of Title 35 Sections**

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Maintained**

6) The objection to the specification made in paragraph 3 of the Office Action mailed 7/27/04 and maintained in paragraph 8 of the Office Action mailed 12/29/05 is maintained for reasons set forth therein.

7) The objection to the specification made in paragraph 9(a) of the Office Action mailed 12/29/05 is maintained for reasons set forth therein.

8) The objection to the specification made in paragraph 9(b) of the Office Action mailed 12/29/05 is maintained for reasons set forth therein.

9) The objection to claim 20 made in paragraph 24 of the Office Action mailed 12/29/05 is moot in light of Applicants' cancellation of the claim.

### **Rejection(s) Moot**

10) The rejection of claim 19 and those dependent therefrom made in paragraph 21 of the Office Action 10/16/06 under 35 U.S.C § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claims.

11) The rejection of claims 16-20 made in paragraph 22 of the Office Action 10/16/06 under 35 U.S.C § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claims.

12) The rejection of claims 17-20 made in paragraph 23 of the Office Action 10/16/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

### **Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)**

13) Claim 22 is rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 22 includes the limitations: 'porous' test strip; 'flowing the urine sample along the porous strip'; 'mobilizing a labeled binding agent capable of binding the C-polysaccharide antigen of *Streptococcus pneumoniae*'; 'the labeled binding agent; having been present in 'a dried state on the porous strip to form a mixture comprising the urine sample and the mobilized binding agent'; 'binding the labeled binding agent and the antigen ... to form complexes' in the mixture; 'flowing the mixture, including complexes if formed, further along the porous test strip'; 'binding at least a portion of the complexes, if present, to antibodies immobilized in at least one zone along the porous test strip'; 'flowing the mixture comprising any non-bound complexes, if present, downstream of the at least one zone'; and 'binding, to antibodies immobilized in a zone downstream of the at least one zone, any non-bound complexes if present, color formation in the downstream zone resulting from the binding is indicative of a symptomatic *Streptococcus pneumoniae* infection in the subject'. However, there appears to be no descriptive support in the specification, as originally filed, for these new limitations.

While there is descriptive support for limitations, such as, 'tagged antibodies', 'conjugates of tagged antibody', 'test strip', 'movably deposited', and 'sample/tagged antibody mixture', there is no descriptive support for the above-identified limitations, and therefore the now claimed method. The narrower limitation of a 'tagged antibody' species does not support the recited broader 'labeled binding agent' genus since a 'binding agent' encompasses agents other than antibodies. The above-identified limitations in the claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or to remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

### **Rejection(s) under 35 U.S.C § 112, Second Paragraph**

**14)** Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 22 is vague, indefinite, and confusing in the limitations: 'the mobilized binding agent' (see line 7) and 'the labeled binding agent' (see line 8). It is unclear how one differs from the other in terms of scope. Is the latter mobilized and the former labeled?

(b) Claim 22 appears to lack proper antecedent basis in the limitation: 'complexes' (see line 10). Are these complexes different from the ones recited in line 8 of the claim? If not, it is suggested that Applicants replace the above-identified limitation with the limitation --the complexes--. The composition of the 'complexes' recited in line 8 of the claim is unclear.

(c) Claim 22 is vague and indefinite in the limitation: 'a portion of the complexes', because it is unclear what is encompassed in this limitation. What constitutes 'a portion of the complexes', and how much of the complexes must be retained such that the resulting product can be considered as 'a portion of the complexes' is not clear.

(d) Claim 22 is vague, indefinite, and confusing in the limitations: 'antibodies immobilized' (see line 11) and 'antibodies immobilized' (see line 15), because how one differs from the other in

scope or immunospecificity is not clear. What elements are these antibodies immunospecific to is unclear. Are these C-polysaccharide antigen-specific antibodies, labeled binding agent-specific antibodies, antibodies specific to at least a portion of the complexes, or antibodies to non-bound complexes? Clarification/correction is requested.

(e) Claim 22 is indefinite and confusing in the limitations: 'further along the porous test strip' (see line 10), 'at least one zone along the porous test strip' (see lines 11 and 12), 'downstream of the at least one zone' (see lines 13 and 14), 'a zone downstream of the at least one zone' (see line 15), and 'the downstream zone' (see line 16). It is unclear what precise areas or zones of the porous test strip do these encompass, and whether or not there is an overlap between the zones?

(f) Claim 22 is indefinite and confusing in the limitation: 'the downstream zone' (see line 16), because it is unclear where exactly the antecedence comes from for this limitation, since there are two earlier recitations in the claim of a downstream zone.

(g) Claim 22 is indefinite and confusing in the limitations: 'non-bound complexes' at lines 13, 15 and 16. The precise composition of these 'non-bound complexes' and the difference in their scope, if any, are unclear.

(h) Claim 22 is vague and indefinite in not reciting in line 1 of the claim the purpose or the objective of the claimed 'method comprising' the recited steps.

### **Remarks**

**15)** Claim 22 stands rejected.

**16)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**17)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application No: 10/083,476  
Art Unit: 1645  
December 2006

**18)** Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Victor Barlow of Art Unit 1645 whose telephone number is (571) 272-0506.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

December, 2006

  
S. DEVI, PH.D.  
PRIMARY EXAMINER